**510(k) Summary**

**Submitter:** Edwards Lifesciences® LLC

**Contact Person:** Lindsay Martin, Regulatory Affairs Associate III
12050 Lone Peak Pkwy
Draper, UT 84020
(801) 565-5388

**Date Prepared:** January 24, 2014

**Trade Name:** Edwards Lifesciences® Femoral Access Venous and Arterial Cannulae

**Classification Name:** Cardiopulmonary bypass vascular catheter, cannula or tubing
Class II (21 CFR §870.4210), Product Code DWF

**Predicate Devices:** K123298: Femoral Access Arterial Cannuulae
K123303: Femoral Access Venous Cannulae

**Device Description:**

The Edwards Femoral Access Venous and Arterial Cannulae with/out Duraflo® coating are wire-reinforced thin-wall polyurethane or PVC cannulae. The wire reinforcement is intended to prevent kinking during use. The clear proximal section of the cannula is unreinforced for clamping and terminates in either a barbed connector for ¼" or 3/8" tubing connection.

The cannulae are available on various sizes and lengths. Each cannula is furnished with one, or in some cases two, dilator(s). In the case of cannulae supplied with two dilators, one is solid and the other is hollow. The hollow dilator will pass over guidewires up to 0.038" (0.97 mm) in diameter. The guidewire, when used, facilitates percutaneous insertion, or insertion under direct visualization. The cannulae tips are tapered for easy insertion.

Some cannulae feature incremental depth markings to aid in proper placement and positioning. Some versions have, as an additional aid to placement, the clear tip section of the cannula

contain two radiopaque barium stripes for visualization. Edwards Femoral Access Cannulae are intended to provide a means of draining the blood flow (venous), or perfusing blood into the body (arterial) of a patient during cardiopulmonary bypass procedures. Each Edwards Lifesciences device is packaged sterile and non-pyrogenic in a sealed, peel-type pouch.

**Intended Use:**

*Intended for femoral venous and arterial access during cardiopulmonary bypass (CPB).*

**Indications For Use:**

Edwards Lifesciences Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short-term (≤ 6 hours) cardiopulmonary bypass. Vessel access (venous or arterial) is left to the discretion of the physician. Femoral access cannulae may be used in pediatric populations or adult populations based on flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates. Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

**Comparative Analysis:**

The basis for this submission is the addition of contraindications to the instructions for use of the Indications for Use statement. No physical changes are being made to these devices. The subject devices have the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices.

**Summary of Changes:**

The basis for this 510(k) submission is to address potential off label usage by adding contraindications to the Instructions for Use for the Femoral Access Arterial and Venous Cannulae labeling cleared under the previous 510(k) submissions (K123298 and K123303). The design of the device remains unchanged. No physical changes are being made to these devices. The subject devices have the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate devices. New contraindications are

being added to mitigate consumer risk for potential off-label use of the Femoral Access Arterial and Venous Cannulae.

**Conclusion:**

The Femoral Access Arterial and Venous Cannulae are substantially equivalent to the cited predicate device(s). Additionally, the Femoral Access Arterial and Venous Cannulae met all pre-determined acceptance criteria to confirm safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 5, 2014

Edwards Lifesciences, LLC.
% Lindsay Martin
Associate III, Regulatory Affairs
12050 Lone Peak Pkwy
Draper, UT 84020 US

Re: K140208
Trade/Device Name:
Fem-Flex II Femoral Arterial Cannula
Fem-Flex Femoral Arterial Cannula
Femoral Access Cannula with Duraflo™ coating
Fem-Flex II Femoral Venous Cannula
Femoral Venous Cannulae
FemTrak Femoral Venous Cannula
Femoral Access Cannula with Duraflo™ coating
Regulation Number: 21 CFR 870.4210
Regulation Name: Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass
Regulatory Class: Class II
Product Code: DWF
Dated: January 29, 2014
Received: February 3, 2014

Dear Ms. Martin,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Statement of Indications for Use

## Indications for Use

510(k) Number (if known): K140208

Device Name: Edwards Lifesciences Femoral Access Venous and Arterial Cannulae

*Caution: Federal law (U. S. A.) restricts this device to sale by, or on the order of, a physician.*

Edwards Lifesciences Femoral Access Cannulae are intended for use in situations which require rapid femoral venous and arterial access for short-term (≤ 6 hours) cardiopulmonary bypass. Vessel access (venous or arterial) is left to the discretion of the physician.

Femoral access cannulae may be used in pediatric populations or adult populations based on flow rate requirements and individual patient anatomy. Please consult labeling to determine pressure drop related to flow rates.

Extracorporeal circuit components with a Duraflo coating are intended for use in cardiopulmonary surgery when a heparin coated blood path is desired.

Prescription Use __x__ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office Of Device Evaluation (ODE)